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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/816,252

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David Walter Wright

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OLIFF & BERRIDGE, PLC
P.O. BOX 320850
ALEXANDRIA, VA 22320-4850

EXAMINER

BOWERS, NATHAN ANDREW

ART UNIT

PAPER NUMBER

1797

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/816,252	Applicant(s) WRIGHT ET AL.	
	Examiner NATHAN A. BOWERS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-64 is/are pending in the application.
- 4a) Of the above claim(s) 31-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-30 and 56-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claim 64 is objected to because of the following informalities: the claim is grammatically disjointed, and is not presented as a single sentence. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 1, 3-12, 18-30 and 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oshiyama (US 4976708) in view of Pawlak (US 5674397).

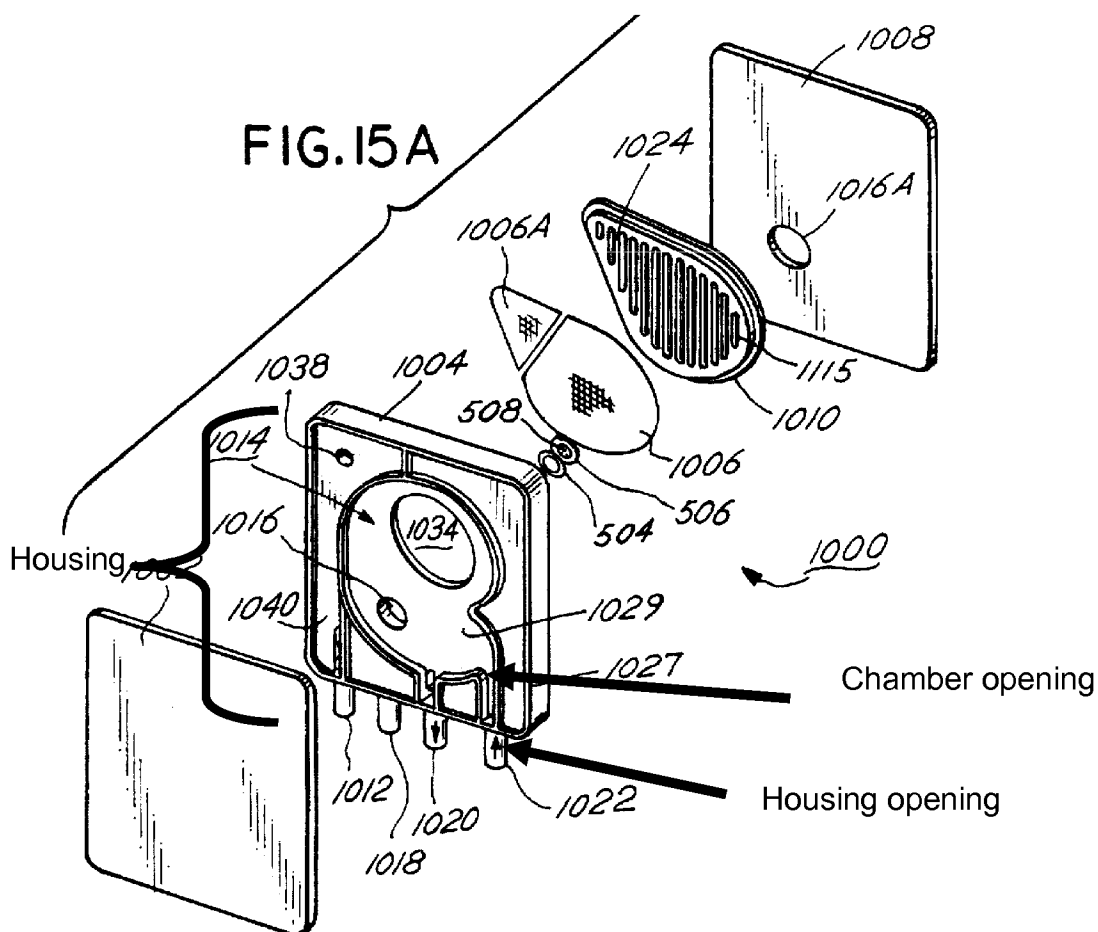
With respect to claims 1, 56-58 and 64, Oshiyama discloses an apparatus for separating gas from a liquid path comprising a chamber (Figure 1:12) having a top, bottom and side walls. A first opening (Figure 1:15) allows gas and liquid to enter the chamber, a second opening (Figure 1:18) is configured to allow gas to exit the chamber, and a third opening (Figure 1:17) is configured to allow liquid to exit the chamber. This is taught in column 4, line 41 to column 6, line 22. The chamber interior is entirely open, and there is no filter to interrupt fluid movement. Although Oshiyama does not expressly indicate that the second chamber opening is precisely in a middle-portion of a top portion (instead Figure 1 depicts it slightly to one side), it would have been obvious to ensure that the second chamber opening is located in a middle-portion of a top portion. Likewise, although Oshiyama does not expressly indicate that the third chamber opening is precisely in a middle-portion of a bottom portion (instead Figure 1 depicts it slightly to one side), it would have been obvious to ensure that the third chamber opening is located in a middle-portion of a bottom portion.

Oshiyama, however, also does not expressly indicate that each of the openings and corresponding channels are formed within the walls of a surrounding housing.

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Rather, Oshiyama teaches that the openings and channels are formed as openings within a flexible envelope.

Pawlak discloses a debubbler that comprises a chamber housing defining a chamber (Figure 15:1029) capable of holding a liquid and gas. Openings and channels are cut into the sidewalls of the housing in order to allow the ingress and withdrawal of fluid and gas streams. This is disclosed in column 27, line 44 to column 28, line 4. Gas and liquid are separated by a membrane (Figure 15:1006), and degassed fluid is removed from one opening (Figure 15:1020) while gas is removed from another opening (Figure 15:1018).



Oshiyama and Pawlak are analogous art because they are from the same field of endeavor regarding gas-liquid separation systems.

At the time of the invention, it would have been obvious to form the envelope disclosed by Oshiyama as a rigid housing that includes openings and channels cut into the walls. Pawlak teaches that this configuration is well known in the art, and is suitable for the effective removal of gases and liquids. The creation of channels formed as cavities within the solid housing and the creation of channels formed as autonomous units exterior to the chamber volume represent functionally equivalent means for adding and withdrawing fluid from the chamber. It would have required only minor structural alterations to the existing Oshiyama housing to provide channels and openings similar to those disclosed by Pawlak, and this alteration would have been accomplished in a predictable manner.

With respect to claims 2-4 and 19, Oshiyama and Pawlak disclose the apparatus in claim 1 wherein the chamber is located within a housing. The outer shell of the chamber walls is considered to represent a housing such that the first, second and third openings cause fluid to move through the chamber and housing.

With respect to claims 5-9 and 20-30, Oshiyama and Pawlak disclose the apparatus in claims 4 and 19. Claims 5-9 and 20-30 further describe various opening and channel orientations that are not expressly set forth by either Oshiyama or Pawlak. However, none of these limitations serve to patentably distinguish the instant invention

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from the cited prior art because the claim 5-9 and 20-30 limitations merely involve rearrangement of parts that are well known in the art. One of ordinary skill would have readily recognized that the Oshiyama and Pawlak channels could be configured so that they are curved, have various vertical sections, and have various horizontal sections. Similarly, one of ordinary skill in the art would have readily recognized that the Oshiyama and Pawlak openings could have been formed on any surface. This is primarily because the rearrangement of these parts does not impact the functionality of the device, but rather is instead a simple design choice.

With respect to claim 10, Oshiyama and Pawlak disclose the apparatus in claim 1 wherein the debubbler is capable of connection with either a tube frame, an organ or tissue transporter, a perfusion device, or a diagnostic device.

With respect to claims 12 and 18, Oshiyama and Pawlak disclose the apparatus in claim 3 wherein tubing is connectable to each of the plurality of openings. This is apparent from Figure 1.

With respect to claim 11, Oshiyama and Pawlak disclose the apparatus in claim 1. Oshiyama teaches that the device is constructed from plastic. Transparent plastic materials are considered to be well known in the art.

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2) Claims 13-17 and 59-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oshiyama (US 4976708) in view of Pawlak (US 5674397) as applied to claims 12 and 58, and further in view of Sadri (US 5494822).

Oshiyama and Pawlak disclose the apparatus set forth in claims 12 and 58 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly state that a sensor is provided for detecting gas moving through the first and/or third housing openings.

Sadri discloses a device for transporting and maintaining an organ that comprises a chamber (Figure 1:25) for holding the organ, a fluid supply line (Figure 1:13) and an oxygenator (Figure 1:6). This is disclosed in column 10, line 34 to column 11, line 6. Column 6, lines 11-20 further state that a bubble trap is provided between the oxygenator and the perfused organ. Sensors (Figure 1:14) monitor gas levels of fluid moving from the bubble trap to the organ chamber. Column 11, lines 50-58 state that the flow rate of perfusate flowing into the organ is altered in response to gas level characteristics measured in the fluid. Column 7, lines 40-60 indicate that the operation of the pumping mechanisms and valves regulating the fluid system are controlled in response to measurements made by the gas sensors. Although Sadri does not specifically disclose the use of an ultrasonic gas sensor, ultrasonic gas sensors are considered to be well known in the art. It would have been obvious to use any known sensor in the apparatus of Sadri.

Oshiyama and Sadri are analogous art because they are from the same field of endeavor regarding culture means.

At the time of the invention, it would have been obvious to equip the apparatus of Oshiyama with a gas monitoring probe capable of interacting with a control system designed to regulate fluid flow to and from the debubbler in response to detected gas levels. Since the intent of the Oshiyama device is to remove gas from a blood stream, one of ordinary skill in the art would have found it obvious to include sensing means capable of determining the efficacy of the system and the extent of gas removal.

Response to Arguments

Applicant's arguments filed 18 February 2009 with respect to the 35 U.S.C. 103 rejections involving Gremel in view of Pawlak have been fully considered and are persuasive. These rejections have been withdrawn.

Applicant's arguments filed 18 February 2009 with respect to the 35 U.S.C. 103 rejections involving Gremel in view of Pawlak have been fully considered and are persuasive. These rejections have been withdrawn.

Please consider the newly made rejections involving the combination of Oshiyama with Pawlak. Oshiyama does not suffer from the deficiencies of the previously cited prior art because Oshiyama discloses a debubbler in which the interior space is not partitioned by a filter that serves to inhibit fluid communication.

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Fini (US 5858015) and Sutherland (US 5061236) references disclose the state of the art regarding gas separation devices.

This is a non-final rejection.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN A. BOWERS whose telephone number is (571)272-8613. The examiner can normally be reached on Monday-Friday 7 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/Nathan A Bowers/
Examiner, Art Unit 1797